

REMARKS

Applicants and their representative respectfully acknowledge the time and courtesy extended by the Examiner during the Interview conducted April 4, 2002. The discussion during the Interview is reflected in the above amendments and below remarks.

The Amendments

Claim 1 is amended to clarify that the composition is "substantially purified of flavones or flavonoids other than isoquercitrin or the other components." Support for this amendment is found in the original specification, for example, at pages 4-5 of the specification. The disclosure makes clear that applicants had isoquercitrin in purified form (e.g., top of page 5) and that they had discovered that isoquercitrin had desired properties not possessed by other flavones or flavonoids. The amendment further clarifies that the "glycoside" option applies to the "other components" and not to isoquercitrin, as was discussed during the Interview. This is supported by original claim 10 of the specification. Support for new claim 26 is found in the original disclosure, for example, in the Example at page 13 and in original claim 12.

It is submitted that the above amendments would put the application in condition for allowance or materially reduce or simplify the issues for appeal. The amendments do not raise new issues or present new matter. The amendments have been made to address issues raised during the Interview – some of which were raised for the first time at the Interview. Thus, they were not earlier presented. Accordingly, it is submitted that the requested amendments should be entered.

The amendments do not narrow the scope of the claims and/or were not made for reasons related to patentability. The amendments should not be interpreted as an acquiescence to any objection or rejection made in this application. To the extent that the amendments avoid the prior art, competitors are warned that the amendments are not intended to and do not limit the scope of equivalents which may be asserted on subject matter outside the literal scope of any patented claims but not anticipated or rendered obvious by the prior art. Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

The Rejection under 35 U.S.C. §102

The rejection of claims 1-7 under 35 U.S.C. §102, as being anticipated by JP 06-183940 is respectfully traversed.

It is believed that the rejection is overcome by the above amendment. The JP reference discloses compositions for use in periodontal work, particularly for treating oral cavities. The compositions may contain isoquercitrin, myricitrin and/or isorhamnetin, all flavonols. The reference, however, fails to disclose a composition containing isoquercitrin and another flavonol component selected from is 5-ethyldeoxyuridine, quercetin, galangin, kaempferol, propolis, chrysin, apigenin, luteolin, acacetin, eriodictyol, quercitrin, catechol, hesperitin, rutin or a glycoside of any of these. The reference also fails to disclose a composition containing isoquercitrin substantially purified from other flavonols or flavones other than isoquercitrin and the other above-stated flavonol component. Additionally, there is certainly no specific example or teaching of a composition containing the purified

components of applicants' invention. In the absence of any such specific example or teaching, there also can be no 35 U.S.C. §102 rejection for anticipation.

Thus, the rejection should be withdrawn (see additional comments on the JP reference below).

The Rejection under 35 U.S.C. §103

The rejection of claims 1-10 and 12-14 under 35 U.S.C. §103, as being obvious over Lanzendorfer (WO 96/18381) in view of Bean (U.S. Patent No. 4,132,782) is respectfully traversed.

The combined teachings of the references fail to teach or suggest a composition of isoquercitrin and another component which is 5-ethyldeoxyuridine, quercetin, galangin, kaempferol, propolis, chrysin, apigenin, luteolin, acacetin, eriodictyol, quercitrin, catechol, hesperitin, rutin, a glycoside of any of the above other components, a vitamin, a carotene or ascorbic acid, where the composition is substantially purified of flavones or flavonoids other than isoquercitrin or the other components.

Lanzendorfer provides a very broad teaching of compositions containing multiple types of components and a vast scope of particular components within each type of component. Amongst the components suggested are flavonoids. Lanzendorfer mentions many specific flavonoids, e.g., at col. 5, line 23, to col. 6, line 4, but there is no specific mention of isoquercitrin. Obviously, there is also no mention or suggestion of isoquercitrin purified from other flavonoids or that isoquercitrin has particular advantages over other flavonoids.

Bean teaches a mountain ash berry extract composition for a utility similar to the

Lanzendorfer compositions. The composition contains isoquercitrin but also contains other various flavonols. It is admitted in the reference that it is not known what component(s) of the extract give the composition its desired properties. Thus, the reference provides no motivation to one of ordinary skill in the art to isolate any of the components, including isoquercitrin, from any of the other components.

It is respectfully submitted that considering the combined teachings of Lanzendorfer and Bean, as a whole, one of ordinary skill in the art would not have been motivated to combine the teachings in any manner suggesting applicants' invention. Merely combining the Bean extract into the Lanzendorfer compositions would not result in applicants' invention because there would be no purification of other flavonoids. Further, one of ordinary skill in the art could not have had a reasonable expectation of success in combining the references in a manner to arrive at applicants' invention. Neither of the references provide a reasonable suggestion that isoquercitrin has any desirable activity. Bean, at most, teaches that isoquercitrin could be the active ingredient in its compositions but so could any of the other dozen or more specific compounds mentioned. This does not provide a reasonable expectation that isoquercitrin is an active component. Lanzendorfer makes no specific mention of isoquercitrin at all. In view of these teachings, there could not have been any motivation to one of ordinary skill in the art to purify isoquercitrin from other flavonoids, except the specific other components recited in applicants' claim. From the teachings of Bean, one would not know if the components they are removing might be the active ones they need. Further, there could be no reasonable expectation of success in making such a purification to arrive at applicants' invention since one of ordinary skill in the art would not know whether they may be removing the active component they desire.

In the absence of the requisite motivation and reasonable expectation of success, it is urged that the combined references, considered as a whole, fail to render the claimed invention obvious to one of ordinary skill in the art. Thus, the rejection under 35 U.S.C. §103 should be withdrawn.

Potential Combination of the JP reference with Lanzendorfer and Bean

During the Interview there was some discussion of whether a combination of the above-discussed JP reference with Lanzendorfer and Bean would render the claimed invention obvious under 35 U.S.C. §103. Applicants respectfully urge that one of ordinary skill in the art would not have the requisite motivation to make such a combination in the first place and that, even if made, the combination would not suggest applicants' invention.

The JP reference is directed to a composition for treating periodontitis and oral cavities. The Bean and Lanzendorfer references relate to compositions for treating the skin for anti-viral purposes. One of ordinary skill in the art would not have any reasonable expectation that components useful for the properties desired in the JP reference would also be useful for the properties desired in Bean or Lanzendorfer. In addition to the absence of similar utilities, there is no other reason of record to support why one of ordinary skill in the art would combine these reference teachings. "Before the PTO may combine the disclosures of two or more prior art references in order to establish prima facie obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art." In re Fine, 5 USPQ 2d 1596,1598-99 (Fed. Cir. 1988). No such suggestion is apparent on the record here.

Even if the JP reference were combined with Lanzendorfer and/or Bean, there would

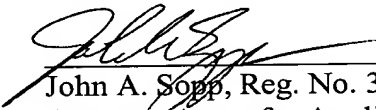
still be no suggestion of applicants' invention. The JP reference does not teach the combination of one of applicants' "other components" with isoquercitrin and none of the references suggest purifying a composition of flavonoids other than the isoquercitrin and the "other component." Thus, even if Bean or Lanzendorfer were relied on to provide the "other component" in combination with the isoquercitrin of the JP reference, there would be no suggestion to purify such combination of components.

Accordingly, no rejection under 35 U.S.C. §103 based on combining all of these references is supported.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,


John A. Sopp, Reg. No. 33,103
Attorney/Agent for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No. : MERCK 2068

Date: April 19, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claim 1 has been amended to read as follows:

1. **(Twice Amended)** A pharmaceutical or cosmetic composition comprising a carrier and synergistically effective amounts of isoquercitrin and another component which is 5-ethyldeoxyuridine, quercetin, galangin, kaempferol, propolis, chrysin, apigenin, luteolin, ~~myricetin~~, acacetin, eriodictyol, ~~isorhamnetin~~, quercitrin, catechol, hesperitin, rutin, a glycoside of any of the above other components, a vitamin, a carotene or ascorbic acid, and where the composition is substantially purified of flavones or flavonoids other than isoquercitrin or the other components.